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(54) Title: SYSTEM AND METHODS FOR REMOVING CLOTS FROM FLUID VESSELS

(57) Abstract

Systems, methods and apparatus for removing arteriosclerotic plaque or clots, such as emboli and/or thrombi, from the interior of a fluid vessel, such as a cerebral or coronary artery, are provided. A coil capture device includes a superelastic coil capable of percutaneously removing plaque and clots from blood vessels without the need for surgical intervention. A radiopaque element is secured over the coil to improve visualization of the coil capture device, which enhances the accuracy of the procedure. A hollow introducing sheath is also provided to facilitate the endoluminally delivery of the coil capture device to the clot region within the patient's vasculature.

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SYSTEM AND METHODS FOR REMOVING CLOTS FROM FLUID VESSELS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present invention is a continuation-in-part of application Serial No. 08/756,145, filed on November 29, 1996 (Attorney Docket 16255-004300), the full disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is directed to systems and methods for treating thromboembolic disorders within the circulatory system. The present invention is particularly useful for percutaneously capturing and removing plaque and other occlusions, such as clots, thrombi, emboli, from fluid vessels, such as the vessels in the cerebral and peripheral vasculature.

The presence of thromboembolic disorders within the body's circulatory system presents significant health hazards such as stroke, pulmonary embolism, peripheral thrombosis, atherosclerosis and the like. These thromboembolic disorders are most often characterized by an occlusion of a blood vessel which is caused by a clot. The clot is typically viscoelastic (jelly-like) and is comprised of platelets, fibrinogen and other clotting proteins. When a blood vessel is occluded by a clot, tissue ischemia (lack of oxygen and nutrients) develops and may progress to tissue infarction (cell death) if the occlusion persists. When the blockage of blood flow becomes sufficiently serious, it is often necessary to intervene and recanalize the blood vessel because occluded blood vessels can cause a variety of clinical manifestations including

myocardial infarction (heart attack), angina pectoris, stroke, intermittent claudication and gangrene.

Numerous techniques are employed for such recanalization. One of the most common surgical techniques is referred to as embolectomy, where the blood vessel is entered through a surgical incision and a device is introduced through the blood vessel for removing the clot and thrombus. Most commonly, a balloon tip device (such as the Fogarty catheter) is introduced through a surgical incision and advanced to the location of the occlusion. The balloon is then inflated at a point beyond the clot and is used to translate the obstructing material back to the point of incision. The obstructing material can then be removed by the surgeon.

While such surgical techniques have been of enormous value, the need to expose a patient to surgery is always traumatic and best avoided when possible. A variety of percutaneous methods have also been utilized for recanalization of blood vessels. One of the most common of such techniques is referred to as balloon angioplasty, where a balloon tip catheter is non-surgically introduced to a blood vessel typically through an introducing catheter. The balloon tip catheter is then advanced to the point of stenosis and inflated in order to dilate the blockage. Balloon angioplasty, thus, does not actually remove stenotic material from the blood vessel, but rather compresses it outwardly in order to increase the available lumen size in the blood vessel. Balloon angioplasty has also been of great value in treating vessel stenosis but is generally not effective for treating acute thromboembolisms. This is because the atheroma and plaque which have been dilated are often subject to rapid restenosis. Even more problematic, the material which is compressed against the wall of the blood vessel will sometimes dislodge and clause an abrupt closure of the lumen, which can be catastrophic.

Other percutaneous canalization techniques have been proposed. Laser angioplasty involves the use of laser energy to ablate stenosis within the blood vessel. Although laser angioplasty has the advantage that the stenotic materials

vaporize and, thus, are not available for restenosis, most laser techniques are limited in their ability to open broad passages within the blood vessels. Other percutaneous techniques involve placing a microcatheter near the clot and infusing streptokinase, urokinase or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolus typically requires hours or days to be successful and thrombolic agents can cause severe hemorrhage in some patients.

Recently, another percutaneous approach has been developed for extracting thrombi and other clots from fluid vessels. This technique involves deforming a coiled device into an elongate configuration within an introducing catheter and endoluminally delivering the coiled device beyond the site of the stenosis within the fluid vessel. The coiled device is then expanded within the blood vessel to its coiled configuration and retracted to ensnare and remove a clot in the vessel. The coiled device typically comprises a wire coil made of a superelastic material with a shape memory (e.g. Nitinol) that is capable of being stretched or otherwise deformed into a smaller diameter or unstable configuration for delivery through the introducing catheter. Typically, the shape memory or superelastic alloy will revert, or attempt to revert, from its unstable configuration to its original, stable configuration upon the application of heat, or upon the removal of a restraint, e.g., the introducing catheter. The clot is extracted from the vessel by moving the expanded coil and the clot proximally into the guiding catheter where it can then be removed from the body or released into a different vessel that does not perfuse a critical organ. This technique has proven advantageous because it provides for the removal of plaque and clots from blood vessels without the need for surgical intervention. In addition, this technique is an improvement over balloon or laser angioplasty because there is much less likelihood of abrupt reclosure of the blood vessel, and it provides for a larger diameter opening through the blood vessel.

Although the coil capture method of removing clots from blood vessels is promising, current techniques suffer

from a number of disadvantages. One such disadvantage is that the shape memory material of the coil is substantially radiolucent (particularly small diameter coils) and, therefore, provides at best a moderate image under fluoroscopic imaging. Thus, it is often difficult to determine when the coil has passed beyond the site of the clot in the body lumen, and when the coil has passed the distal tip of the delivery catheter. In addition, the surgeon may have difficulty in monitoring the expansion of the coil to determine if the coil has completely or partially deformed into a coiled configuration suitable for capturing and removing the clot or thrombus from the walls of the fluid vessel.

Another disadvantage with current techniques of the coil capture method for removing clots is that it is often difficult to deliver the superelastic coil through a delivery catheter, (especially a microcatheter) because the coil continually expands against the wall of the catheter. This continual expansion increases the friction between the coil and the delivery catheter making it difficult, if not impossible, to extend the device through the catheter, particularly in tortuous body lumens.

2. Description of the Background Art

U.S. Patent Nos. 4,706,671 and 5,011,488 both describe the use of a coiled section for removal of thromboembolic material. The latter patent teaches the use of a coiled section that is fixed in both the proximal and distal ends since the operating device can change the shape and size of the coils. U.S. Patent Application Serial No. Unassigned, titled "Clot Capture Coil" Y. Pierre Gobin and Jeffrey P. Wensel, assigned to the Regents of the University of California, filed October 2, 1996 describes the use of a shape memory alloy coil, such as Nitinol, that reforms to an original coil configuration when the coil is moved outside the catheter lumen. U.S. Patent No. 4,706,671 discloses a collapsible coil for extracting a clot. U.S. Patent Nos.

5,011,488, 4,873,978 and 4,650,466 also disclose methods of extracting thrombus from the vasculature.

U.S. Patent No. 5,209,703 describes an over-the-wire balloon catheter with a radiopaque marker thereon. U.S. Patent No. 5,419,324 describes a board which rests under the patient and has one or more markers that can be detected under fluoroscopy to pinpoint various locations of interest in the blood vessel. U.S. Patent No. 5,464,438 describes vascular grafts and shunts that are lined or plated with gold to form a non-thrombogenic surface. European patent application No. 679,372 and WO 95/03010 describe radiopaque markers for a stent.

The properties of nickel/titanium shape memory alloys are described by T.W. Duerig and A.R. Pelton in an article entitled "TI-NI Shape Memory Allows", a reprint from Materials Properties Handbook, Titanium Alloys, ASM International 1994, and by C.M. Jackson, H.J. Wagner and R.J. Wasilewski in an article entitled "55-Nitinol-The Alloy with a Memory: Its Physical Metallurgy, Properties and Applications", Technology Utilization Office, National Aeronautics and Space Administration (1972).

Surgical devices incorporating elastic materials, such as shape memory alloys, are described in U.S. Patent Nos. 5,254,130, 5,486,183, 5,345,937, 4,512,338 and 4,601,283, European Patent Application No. 0 688 545 A1, and Canadian Patent Application No. 2,079,944. U.S. Patent No. 4,935,068 teaches some of the fundamental properties of shape memory alloys. U.S. Patent No. 4,665,906 to Jervis describes medical devices, including catheters and cannulas, which make use of the pseudoelastic or stress-induced martensitic (SIM) properties of certain shape memory alloys.

SUMMARY OF THE INVENTION

The present invention provides systems, methods and apparatus for removing arteriosclerotic plaque or clots, such as emboli and/or thrombi, from the interior of a fluid vessel, such as a cerebral, coronary, or peripheral artery or vein.

The systems and methods of the present invention include a coil capture device capable of percutaneously removing plaque and clots from blood vessels without the need for surgical intervention. The present invention provides improved visualization of the coil capture device to enhance the accuracy of the procedure. In addition, the present invention provides improved delivery apparatus and methods to facilitate the endoluminally delivery of the coil capture device to the clot region within the fluid vessel.

In one aspect of the invention, a clot capture device includes an elongate member having proximal and distal ends and a superelastic coil at the distal end. The superelastic coil comprises a substantially radiolucent material, preferably a shape memory alloy material such as Nitinol, that allows the coil to be deformed into a substantially elongate configuration for endoluminal delivery within an introducing catheter. The superelastic coil will return to its original coiled configuration when the coil is removed outside the catheter lumen. According to the present invention, one or more radiopaque element(s) are secured over the radiolucent portion of the coil to improve the fluoroscopic image of the coil during a clot removal procedure. Since shape memory alloys, particularly Nitinol, generally provide a poor to moderate image under fluoroscopic imaging, the radiopaque element(s) allow the surgeon to monitor the coil within the body lumen to facilitate the proper positioning of the coil within the body lumen. In addition, the radiopaque element(s) allow the surgeon to ensure that the coil has fully expanded to a suitable coiled configuration for capturing and removing the clot from the fluid vessel. Alternatively, the element(s) will allow the surgeon to partially deploy a section of the coil, which may be desired for strategic sizing within a vessel.

The radiopaque element(s) will comprise a material that provides a high-contrast image when viewed under fluoroscopy, ultrasound, or some other surgical imaging modality, so as to improve the surgeon's visualization of the coil within the patient's vasculature. Preferably, the

radiopaque element(s) extends substantially continuously over the radiolucent portion of the coil. Since the entire coil will typically comprise the shape memory or radiolucent material, the radiopaque element(s) are typically secured over the entire coil. This allows the surgeon to visualize the entire coil in its expanded or partially expanded configuration to ensure that the coil is properly positioned and expanded to capture the clot within the fluid vessel. For example, the coil may have a conical shape that increases in diameter in the proximal direction. In this embodiment, the surgeon may deploy only a distal portion of the coil to ensure that the coil has the appropriate size for removing the clot without causing injury or trauma to the body vessel.

In a preferred configuration, the radiopaque element comprises a single, elongate element, such as a wire, wrapped around the coil substantially continuously along the entire length of the coil. Alternatively, the radiopaque element may comprise a coating, plating or film adhered to the coil along its length. However, applicant has found that the radiopaque wire works more effectively with superelastic coils that change shape. Preferably, the radiopaque wire is attached to the coil wire at either end and wrapped loosely or secured directly to the length of the wire therebetween. Thus, as the coil expands and collapses within the lumen, the radiopaque wire will remain secured along the length of the coil. In an exemplary embodiment, the wire comprises platinum, although it will clearly be recognized that the wire may comprise a variety of radiopaque materials other than platinum, such as gold, tantalum and the like.

In an exemplary embodiment, the present invention comprises a clot capture system which includes a catheter with at least one inner lumen having an outer diameter selected to pass through the patient's anatomic lumen. In one embodiment, the catheter is a microcatheter sized to pass through extremely small lumens, such as cerebral arteries, peripheral arteries and veins and the like. The superelastic coil is preferably integral with a superelastic insertion mandrel that allows the surgeon to advance the coil independently of the

catheter. Alternatively, the coil may be attached to a separate rigid or elastic insertion mandrel. In use, the coil is elongated and retracted within the catheter and both the coil and catheter are advanced to the target site beyond the clot in the body lumen. The catheter is then retracted proximally relative to the coil so that the coil is allowed to expand outward into an expanded coiled configuration. The surgeon can radiographically view the radiopaque element(s) to monitor the expansion of the coil and determine when the coil has reached the suitable size and configuration for removing the clot in the body lumen. The coil is then retracted proximally to capture the clot, and both the delivery catheter and the coil are withdrawn until the clot can be removed from the patient or released into a different vessel that does not perfuse a critical organ

In another aspect of the invention, the clot capture system includes a hollow introducing sheath having a lumen diameter selected to radially constrain the elastic coil and an outer diameter selected to pass through the catheter lumen. Preferably, the introducing sheath has a length equal to or greater than the length of the delivery catheter so that the surgeon can manipulate the proximal end of the sheath while the distal end extends beyond the distal tip of the catheter. The sheath prevents the coil from contacting the inner walls of the catheter lumen, which reduces the friction therebetween and facilitates delivery of the coil to the target site in the vasculature. Specifically, the coil is elongated and retracted into the sheath similar to the method described above relative to the catheter. A mandrel and sheath are preferably coated with a lubricant, such as a hydrophilic coating, to increase the lubricity therebetween and facilitate movement of the wire coil relative to the sheath. The sheath and coil are then introduced into the catheter and the entire system is endoluminally delivered to the target site. At this point, both the catheter and sheath are withdrawn proximally so that the coil can expand into its coiled configuration. The entire system is then withdrawn proximally to capture and remove the clot.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 schematically illustrates a clot capture coil system according to the present invention incorporating an introducing catheter and a coil capture apparatus;

Fig. 2 is an enlarged view of a distal end portion of the clot capture coil apparatus of Fig. 1, illustrating a coil and a radiopaque element for use with fluoroscopic imaging of the coil;

Fig. 3 schematically illustrates another clot capture coil system according to the present invention additionally incorporating an introducer sheath for facilitating deployment of the coil in the patient's vasculature; and

Figs. 4A-4E illustrate a method of removing a clot or thrombus within a body lumen with the coil system of Fig. 3 according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides systems, methods and apparatus for removing plaque, clots or thrombus from blood vessels. In particular, the present invention provides a clot capture system for percutaneously removing a clot or thrombus from cerebral lumens in neurological procedures to treat stroke, embolic events, aneurysms, tumors, arteriovenous malformations, fistula and the like within the brain. Of course, it will be recognized that the present invention can be used for a wide variety of medical applications such as interventional cardiological procedures in the coronary arteries, peripheral vasculature and the like, but they are particularly useful for inner cranial selective catheterization.

The capture coil system of the present invention includes a capture coil device sized and configured for endoluminal delivery through an inner lumen of a delivery catheter. The delivery catheter will comprise a catheter body having dimensions and geometry selected for the specific

fluid vessel containing the clot or thrombus. The catheter body will typically have a length in the range from about 40 cm to 200 cm, usually having length in the range from about 60 to 175 cm. The delivery catheter will typically have a small outside diameter of 4 mm (12 F) preferably below 2.67 mm (8 F), and frequently as small as 1 mm (3 F) and below such as those used in neurological, diagnostic and interventional procedures. Such small catheters will also be useful for other procedures such as gynecological procedures, thoracic procedures, general interventional radiological procedures, and the like for access to small vasculature as necessary. The catheter body will define an inner lumen typically having a diameter in the range from about 0.1 to 3.6 mm usually being in the range from about 0.3 to 2.5 mm with catheters having larger outside diameters usually having larger lumen diameters. Constructions of the present inventions are not limited to such small diameter catheters and will be useful for larger diameter catheters as well, such as vascular guiding catheters which may have outside diameters larger than 4 mm. The catheter body will usually be straight along all or most of its length. By straight, it is meant that the catheter body will assume a straight or linear configuration when freed from external bending forces. The catheter body, however, will be highly flexible so that it will be able to pass through the tortuous regions of the patient's vascular.

The catheter body will usually be formed by extrusion of an organic polymer, such as polyethylenes, polyvinylchlorides, polyurethanes, polyesters, polytetrafluorethylenes (PTFE), and the like. Optionally, the catheter body may be formed as a composite having a reinforcement material incorporated within the polymeric body in order to enhance its strength, flexibility and toughness. Suitable reinforcement layers include braiding, wire mesh layers, and the like. The catheter body will typically be formed with at least one continuous lumen extending from the proximal end to the distal end being provided for receiving a guide wire and the capture coil device. Of course, the catheter body may include additional lumens for separately

receiving the guide wire and the capture coil device or for delivery of a fluid into the vessel.

A proximal hub will normally be provided at the proximal end of the catheter body. The hub will serve to provide access to the catheter lumen, typically including at least one port. The port will be adapted for receiving the guide wire and the capture coil device. In addition, the port may be adapted for connection to a source of therapeutic or diagnostic fluid. Alternatively, the hub may include first and second separate ports for these functions. The construction of such hubs and connection ports is conventional. For example, the hub may be coupled to a Y-shaped rotating hemostatic valve for providing the guide wire, capture coil device and fluid delivery functions.

The capture coil device of the present invention includes an insertion mandrel and a superelastic coil at the distal end of the mandrel. The mandrel and the coil are preferably formed as a single, integral piece, but they may also be formed separately and then coupled together with suitable bonding techniques, such as soldering, adhesives and the like. Insertion mandrel is preferably relatively stiff to support the coil and allow independent movement of the coil relative to the delivery catheter. In the preferred embodiment, the insertion mandrel comprises a shape memory or superelastic alloy, such as Nitinol, and is preferably formed from the same piece of solid wire as the coil, having a wire diameter of about 0.006" to about 0.38". Other materials can be used for insertion mandrels, such as a hard plastic, stainless steel and the like. The insertion mandrel is preferably 10 to 20 cm longer than the catheter and the introducer sheath (discussed below) so that the operator of the device can control the insertion mandrel by gripping the proximal end which extends from the proximal end of the catheter.

The coil comprises a flexible solid elastic or superelastic material which has shape memory, i.e., it can deform to a substantially elongate position and then return to a resting coiled configuration. Among metallic alloys, such

as Nitinol™, the ability to possess shape memory is a result of the fact that the alloy undergoes a reversible transformation from an austenitic state to a martensitic state. The transformation between states may be caused by a change in temperature, sometimes referred to as a thermoelastic martensitic transformation. An article made from such an alloy can be deformed from its original configuration to a new configuration when cooled below the temperature which the alloy is transformed from the austenitic state to the martensitic state. The temperature at which this transformation begins is usually referred to as M_s and the temperature at which it finishes M_f. When an article thus deformed is warmed to the temperature at which the alloy starts to revert back to austenite, referred to as A_s, the deformed object will begin to return to its original configuration (A_f being the temperature at which the reversion is complete). A further description of this phenomenon can be found in U.S. Patent No. 4,935,068 to Duerig, the complete disclosure of which is incorporated herein by reference.

Under certain conditions, shape memory alloys are known to display pseudoelasticity or superelasticity, typically referred to as stress-induced martensite. When a shape memory alloy is exhibiting stress-induced martensite, it is stressed at a temperature above M_s (so that the austenitic stage is initially stable), but below M_d (the maximum temperature at which martensite formation can occur even under stress). The alloy first deforms elastically, and then at a critical stress, begins to transform by the formation of a stress-induced martensite. If the temperature is above A_s, the martensite is unstable and transforms back to austenite upon release of the constraint. A further description of stress-induced martensite stent medical devices can be found in U.S. Patent No. 4,665,906 to Jervis, the complete disclosure which is incorporated herein by reference.

The material for the shape memory or superelastic alloy will be selected according to the desired characteristics of the coil. Preferably, the shape memory or superelastic alloy will comprise a nickel titanium based

alloy, which may include additional elements which affect the characteristics of the prosthesis, such as the temperature at which the shape transformation occurs. For example, the alloy may incorporate additional metallic elements, such as copper, cobalt, vanadium, chromium, iron or the like. Alternatively, the coil may comprise a shape memory polymer.

In a preferred embodiment, the coil is made out of a solid Nitinol wire with a wire diameter of about 0.002" to 0.005". Nitinol is preferred because of its superelasticity and shape memory. However, other solid materials that are also elastic or superelastic and have shape memory can also be used such as some synthetic plastics, metallic alloys and the like. To manufacture the coil, a Nitinol wire is wrapped around a mandrel into the coil configuration and then heated to appropriate temperatures so that the Nitinol wire adopts the coil configuration as its resting shape upon cooling. The coiled diameter of the coil in its expanded configuration can vary depending on the size of the occluded vessel. The coiled diameter can range from about 1 mm for small vessels to about 30 mm for large vessels such as the pulmonary arteries or inferior vena cava. Usually, the coil will have conical shape such that it has a smaller diameter at its distal end of about 0.5 to 15 mm and a larger diameter at the proximal end of about 2.0 to 30 mm. The length of the coil varies in ranges from about 3 to 100 mm in the proximal to distal direction. Because of the superelastic properties of Nitinol coil, the coil can be extended to a substantially linear configuration with the use of minimal force and then reform to its natural resting configuration when the force is removed.

The coil may have a variety of different shapes in the expanded configuration depending on the coil's function (i.e., the type of plaque or clot, the size and function of the blood vessel, etc.). Typically, the coil will assume a conical or helical shape in the expanded configuration to serve as a scoop collector or trap to gather the thrombus or clot material for pulling through the anatomical lumen for its removal. Alternatively, the coil may have a cylindrical shape, barrel shape, an inverted cup shape, cone shape, helix,

double helix or combinations thereof. Suitable coil configurations are disclosed in patent application to "Clot Capture Coil", filed October 2, 1996, the complete disclosure of which has previously been incorporated herein by reference. Preferably, at least a portion of the coil will have a diameter that is slightly larger than the inner diameter of the fluid vessel so that this portion exerts a slight force against the inner vessel wall. Thus, when the coil is retracted proximally through the vessel, it will capture and remove substantially all of the clot or thrombus material that clings to the inner vessel wall. Since the thrombus material is a relatively thick jelly like material, it will generally stay within the coils as it is being removed.

The clot capture device of the present invention includes one or more radiopaque element(s) secured over the coil to provide a sharp contrast so as to define a pattern which indicates the coil position when the coil is imaged within the patient body. The radiopaque element(s) should not interfere with the radial expansion of the coil from the radially compressed elongate configuration to the radially expanded coiled configuration. On the other hand, the elements should provide a relatively sharp image along substantially the entire length of the coil so that the surgeon can accurately monitor the positioning and expansion of the coil.

The radiopaque element(s) will comprise a material that provides a high-contrast image when viewed under fluoroscopy, ultrasound, or some other surgical imaging modality, so as to improve the surgeon's visualization of the coil within the patient's vasculature. Preferably, the radiopaque element(s) extend substantially continuously over the radiolucent portion of the coil. Since the entire coil will typically comprise the shape memory or radiolucent material, the radiopaque element(s) are typically secured over the entire coil. This allows the surgeon to visualize the entire coil in its expanded configuration to ensure that the coil is properly positioned and expanded to capture the clot within the fluid vessel. The radiopaque element may comprise

a variety of materials, such as platinum, platinum alloys, gold, tungsten, iridium, tantalum and the like. Preferably, the element comprises platinum or a platinum alloy.

In a preferred configuration, the radiopaque element comprises a single, elongate element, such as a round or flat wire, ribbon or a small braid of fine wires, wrapped around the coil substantially continuously along the entire length of the coil. The radiopaque wire is connected to the coil at its proximal and distal ends and freely wrapped around the wire to avoid interference with coil as it moves between the expanded and linear configurations. Preferably, the wire is soldered to the coil, although it may be bonded by other methods, such as adhesives, welding, mechanical locks, etc. The radiopaque wire may also be attached directly to the coil along its entire length. In addition, it should be recognized that the present invention may include more than one radiopaque wire or ribbon secured to coil. For example, the wires can be connected to each other and then wrapped around the coil, or they may be wrapped around the coil sequentially.

Alternatively, the image contrast of the coil element may be improved by selectively thickening, plating or coating the coil with a high contrast material, such as gold, platinum, tantalum, a polymer loaded with radiopaque filler material or the like. In addition, other embodiments may be used, such as platinum marker bands around the distal and proximal ends of the coil. However, applicant has found that it is advantageous to mark the entire coil element, rather than only the proximal and distal ends.

The introducer sheath of the present invention is preferably a single piece polyimide tubing with a strain relief at the proximal end to facilitate handling of the sheath. Alternatively, the sheath may comprises almost any other thermoplastic material, such as polyolefins, polyethylenes, teflons, pebax, hytrels, thermoplastic elastomer materials and the like. The sheath may also comprise a polyimide tubing with a stainless steel (or other suitable material) embedded coil or microbraid therein. Rather that a single piece, the sheath may be made of a two or

three part system for varying flexibility along its length. For example, the sheath may comprise a stainless steel hypotube at the proximal end connected to a polyimide tubing at the distal end, or a thick wall polyimide tubing at the proximal end coupled to a thinner walled polyimide tubing at the distal end or combinations thereof.

Referring now to Figs. 1 and 2, a coil capture system 2 includes a coil capture device 4 for capturing and removing a clot or thrombus in an anatomical lumen and a delivery catheter 6 for percutaneously delivering the capture coil device 4 to the clot region of the anatomical lumen. Delivery catheter 6 comprises a catheter body 12 having an axial lumen 14 for receiving capture coil device 4 and a guide wire (not shown). Inner lumen 14 includes a capture coil/guide wire port 16 at its distal end and a proximal hub 18 at its proximal end. The hub 18 includes a capture coil/guide wire port 20 and a fluid delivery port 22 which both communicate with axial lumen 14.

Coil capture device 4 includes an insertion mandrel 24 and a coil 26 connected to the distal end 25 of mandrel 24. Preferably, coil 26 and mandrel 24 are a single, integral piece of wire. However, the coil and mandrel welded to the distal end 25 of mandrel 24, although other means of permanently or semi-permanently bonding coil 26 to mandrel 24 can be used, such as crimping, gluing, screwing, welding, soldering, and the like. As shown in Fig. 1, mandrel 24 has a length selected to extend from port 20 of hub 18 through distal port 16 of the catheter lumen 14 so that distal end 25 of mandrel 24 can be manipulated from a proximal end 32 extending through hub 18.

As shown in Fig. 2 coil 26 has a proximal end 34 coupled to the distal end 25 of mandrel 24, which is advantageous for removing clots in small and/or tortuous vessels. Coil 26 preferably has a conical shape having a proximal portion 28 with a diameter selected to be slightly larger than the inner diameter of the anatomical lumen and the diameter of the coils decreasing distally to the free end 36. Of course, coil 26 may have a variety of other shapes, such as

a barrel shape, an inverted cone shape with the diameter of the coils increasing distally, an inverted cup in which the diameter of the coil is substantially constant until near the distal end, a double helix coil useful for large clot removal and the like. Preferably, the coil is a single piece of wire, although it may comprise more than one wire piece with each piece coupled to adjoining wire pieces at their ends.

Coil capture device 4 further includes a radiopaque wire 38 coupled, e.g., welded, to the proximal and distal ends 34, 36 of coil 26 and wrapped around coil 26 along its entire length therebetween. In the preferred embodiment, wire 38 is not directly secured to coil 26 although wire 38 could be secured at one or more points between proximal and distal ends 34, 36. As shown in Fig. 2, radiopaque wire 38 has a substantially smaller cross-sectional or elemental diameter than the elemental diameter of coil 26.

Referring to Fig. 3, another embodiment of the present invention will now be described. As shown, a coil capture system 2' includes a delivery catheter 6 and a coil capture device 4 similar to the previous embodiment. In this embodiment, system 2' further includes an introducing sheath 60 for facilitating introduction and delivery of the coil device 4 through catheter 6 to the target site within the patient's vasculature. The introducer sheath 60 preferably has an axial lumen 62 with a diameter selected to radially constrain the elastic coil 26 and an outer diameter selected to pass through the catheter lumen 14. Usually, sheath 60 will have an inner diameter from about 0.001 to 0.01 inch, preferably about 0.005 to 0.02 inch and an outer diameter from about 0.01 to 0.1 inch, preferably about 0.009 to 0.025 inch. The sheath 60 prevents the coil 26 from contacting the inner walls of the catheter lumen 14, which reduces the friction therebetween and facilitates delivery of the coil 26 to the target site in the vasculature. Introducer sheath 60 preferably has a length which is longer than the length of the catheter 6 so that the surgeon can manipulate a distal end 64 of sheath 60 by pulling or pushing on the proximal end 66 of

the sheath. Usually, the sheath will have a length of about 160 to 180 cm and preferably about 175 cm.

Introducer sheath 60 is preferably made from a polyimide tubing but it can also be made from a variety of polymers of composite structure such as braided or coiled polymers. The mandrel 24 and introducer sheath 60 will preferably both be coated with a lubricant, such as a hydrophilic coating, to increase the lubricity therebetween and facilitate movement of the wire coil relative to the sheath. In this manner, the coil device experiences very little friction with respect to the sheath and the device does not contact the microcatheter which minimizes friction therebetween. The coil 26 will usually not be coated with the lubricant because the lubricant may tend to reduce the friction between the coil 26 and the clot, making it more difficult to remove the clot from the body vessel. Introducer sheath 60 advantageously allows the surgeon to deliver coil 26 through the deliver catheter without a lubricous coating because the coil 26 does not move axially relative to the sheath as the sheath 60 and coil 26 are delivered through the delivery catheter to the target site.

Referring now to Figs. 4A-4E, use of the coil capture system 2' of the present invention in clearing a region of thrombus or clot from a blood vessel BV will be described. A lubricant is applied to mandrel 24 and the outer surface of sheath 60, and the coil 26 is elongated and backloaded into the sheath 60. The sheath 60 and coil 26 are then introduced into the catheter 2' and the entire system is endoluminally delivered to the target site. The catheter system 2' will be percutaneously introduced to the blood vessel BV in its fully retracted or elongated configuration. Non-surgical introduction is accomplished by using an introducing catheter to guide the vascular catheter to the desired blood vessel. The introducing catheter is typically advanced to the target site over a separate, movable guide wire. Suitable methods for percutaneously introducing the catheter to both peripheral and coronary blood vessels are

well known in the art and amply described in the medical and patent literature.

As shown in Fig. 4A, the distal end portion 40 of the delivery catheter 2 is passed through a thrombus or viscoelastic clot 50 in the blood vessel BV such that the distal end is extended distally of this region. Once the catheter 6 is in place, superelastic coil 26 and introducer sheath 60 are introduced into the catheter 6 and advanced to the distal tip of the catheter 2 until the sheath tip 66 emerges from the distal end of catheter distal of the clot within the fluid vessel (Fig. 4B). This can be fluoroscopically monitored by viewing radiopaque element 38 on coil 26. Once sheath 60 is free from catheter, the Nitinol coil 26 can be advanced free of the sheath 60 as shown in Fig. 4C. As the capture coil 26 advances past the distal tip in the catheter, the shape memory or superelastic material will cause the coil to expand into the enlarged configuration. The coil 26 deploys and deforms into its natural configuration outside the distal end of introducer sheath 60. The coil may be deformed due to stress induced martensite (i.e., by removing the coil from the delivery catheter), or by temperature induced martensite by the increased body temperature within the blood vessel.

Once the coil 26 has established its natural state, the clot is then retrieved by translating the insertion mandrel 24 along with the catheter 2 proximally, as shown in Fig. 4D. When the clot capture coil 26 is pulled proximally, the clot 50 becomes ensnared. Additionally, while pulling proximally on the insertion mandrel 24, the coil 26 may be rotated by rotating the insertion mandrel 24 to transfix the clot 50 by corkscrewing the clot into the coils (see Fig. 4E). The viscoelastic properties of the clot 50 allow the clot 50 to be captured within the side coils and to be pulled down using the most distal coils as the capture cup. The radiopaque element 38 extending along the coil 26 facilitates fluoroscopic viewing of the coil 26 by the surgeon during this procedure.

WHAT IS CLAIMED IS:

1. A clot capture device comprising:

an elongate member having a proximal end, a distal end, and a superelastic coil at the distal end, wherein at least a portion of the coil comprises a radiolucent material; and

a radiopaque element secured over at least a portion of the radiolucent portion of the coil.

2. The device of claim 1 wherein the radiopaque element extends substantially continuously over the radiolucent portion of the coil.

3. The device of claim 1 wherein substantially the entire coil comprises a radiolucent material, the coil having proximal and distal ends and an elongate portion therebetween, the radiopaque element being secured over the proximal and distal ends and at least partially over the elongate portion.

4. The device of claim 1 wherein the radiopaque element comprises an elongate element wrapped around the coil substantially continuously along the entire length of the coil.

5. The device of claim 4 wherein the elongate element has a diameter substantially smaller than a diameter of the coil.

6. The device of claim 5 wherein the elemental diameter of the coil is about 0.002 to 0.005 inch and the elemental diameter of the radiopaque element is about 0.001 to 0.002 inch.

7. The device of claim 1 wherein the radiopaque element comprises metal and the radiolucent material comprises a shape memory alloy.

8. The device of claim 1 wherein the superelastic coil comprises Nitinol™.

9. The device of claim 1 wherein the elongate member is an insertion mandrel, the superelastic coil being connected to a distal end of the insertion mandrel.

10. The device of claim 1 wherein the superelastic coil is movable between a delivery linear configuration and an expanded coiled configuration for capturing and removing a clot from an anatomical lumen.

11. The device of claim 10 wherein the superelastic coil exhibits stress induced martensite such that the coil, after being deformed by an applied stress, returns to the expanded coiled configuration upon release of the applied stress.

12. A clot capture system comprising:

a catheter with at least one lumen; and

a clot capture device having an elongate shaft with a proximal end, a distal end and an outer diameter selected to pass through the catheter lumen, the clot capture device having an superelastic coil at the distal end comprising a shape memory alloy movable from a substantially elongate configuration and an expanded coiled configuration for removing and capturing a clot from an anatomical lumen;

wherein at least a portion of the coil comprises a radiopaque material.

13. The clot capture system of claim 12 wherein at least a portion of the coil comprises a radiolucent material, the system further comprising a separate radiopaque element secured over the radiolucent portion of the coil.

14. The clot capture system of claim 12 further comprising a hollow introducing sheath having a lumen diameter

selected to radially constrain the elastic coil and an outer diameter selected to pass through the catheter lumen.

15. The system of claim 12 wherein the catheter has an outer diameter selected to pass through a cerebral lumen.

16. A clot capture system comprising:

a catheter with at least one lumen;

a clot capture device having an elongate shaft with a proximal end, a distal end and an elastic coil at the distal end; and

a sheath having a lumen diameter selected to radially constrain the elastic coil and an outer diameter selected to pass through the catheter lumen.

17. The system of claim 16 wherein the catheter has an outer diameter selected to pass through a cerebral or peripheral lumen.

18. The system of claim 16 wherein the coil is movable between a substantially elongate configuration and an expanded coiled configuration for removing a clot from an anatomical lumen.

19. The system of claim 18 wherein the coil comprises a shape memory alloy movable into the linear delivery configuration upon the application of stress, and into the expanded configuration upon the removal of said stress.

20. The system of claim 16 wherein the sheath has a length that is greater than a length of the catheter.

21. A method for removing a clot from a fluid vessel within a patient comprising:

positioning a superelastic, radiolucent coil at a target site near a clot within a fluid vessel;

radiographically viewing a radiopaque element secured over at least a portion the coil; and

withdrawing the coil to capture and remove the clot from the fluid vessel.

22. The method of claim 21 further comprising:

constraining the superelastic coil into a substantially linear configuration;

endoluminally delivering the coil to the target site; and

allowing the coil to expand to a resting coiled configuration within the fluid vessel.

23. The method of claim 21 further comprising securing a radiopaque wire to proximal and distal ends of the coil and wrapping the radiopaque wire around the coil.

24. The method of claim 23 wherein the wire comprises metal and the coil comprises a shape memory alloy.

25. The method of claim 22 further comprising:

constraining the superelastic coil into a substantially linear configuration within a hollow introducing sheath;

positioning a distal portion of a delivery catheter at the target site; and

advancing the sheath and the coil through the delivery catheter to the target site.

26. The method of claim 22 wherein the fluid vessel comprises a cerebral artery.

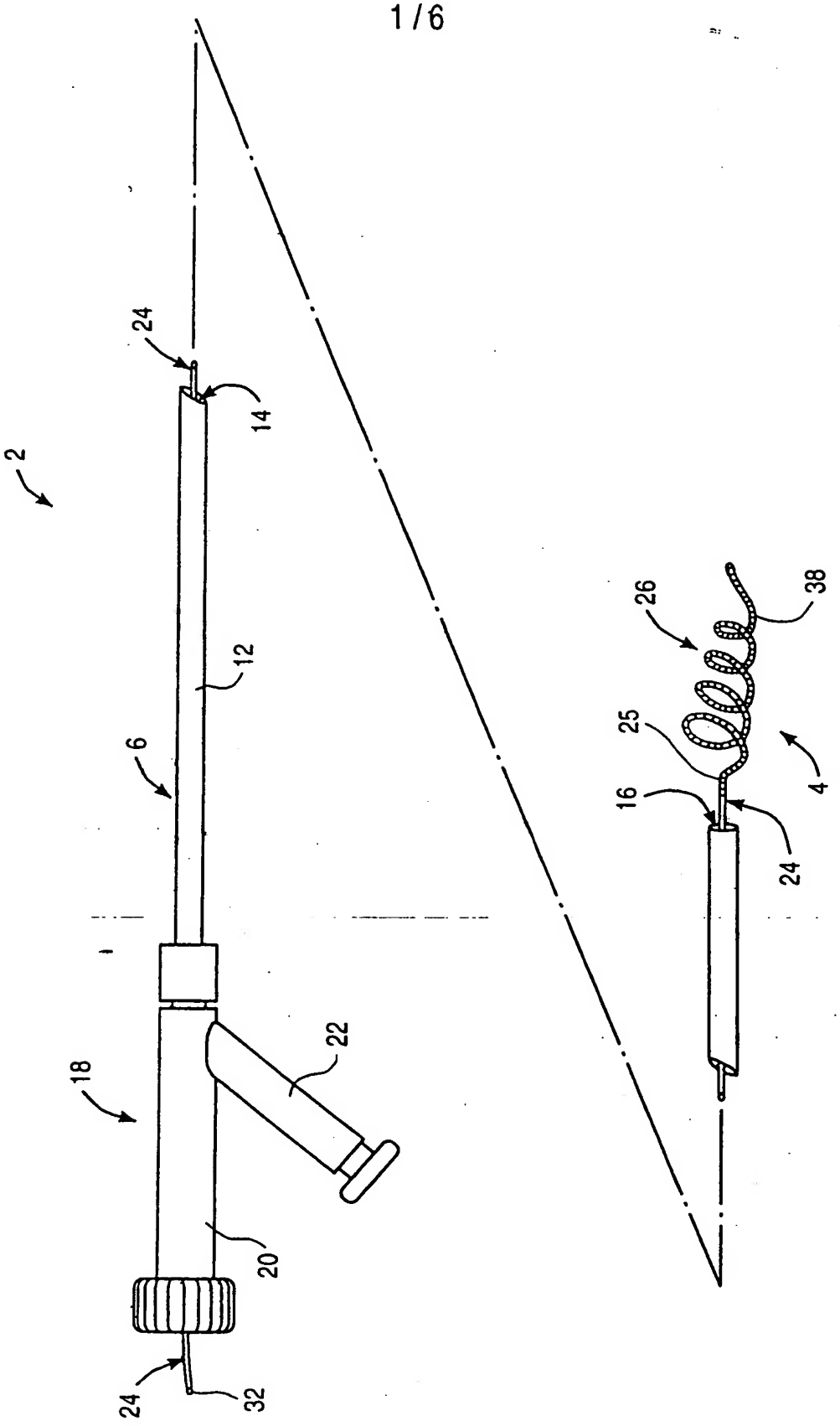

FIG. 1

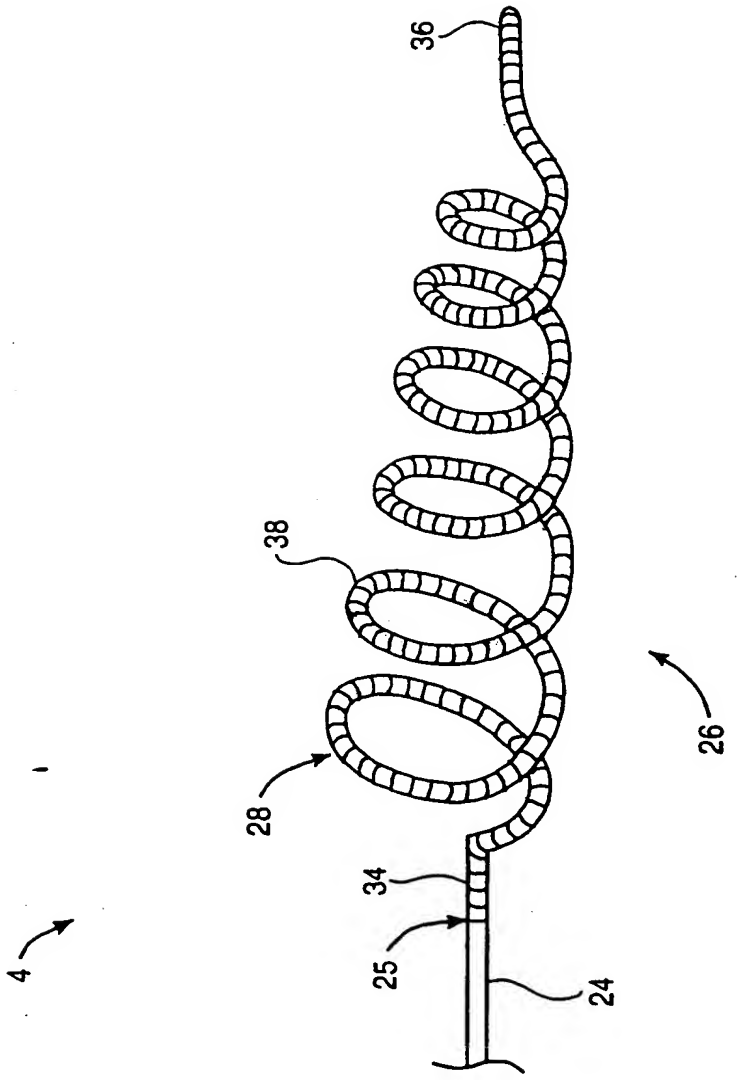

FIG. 2

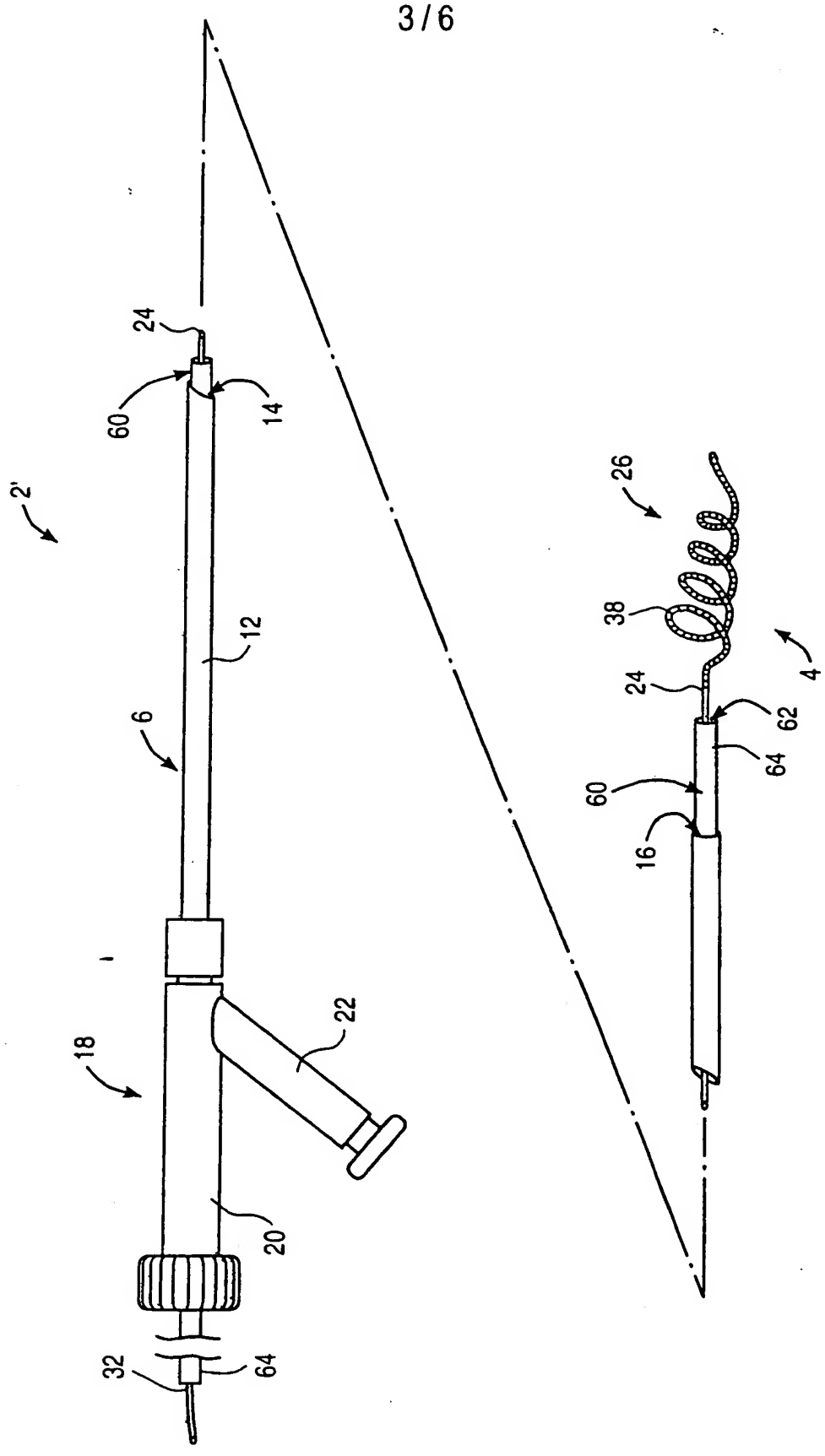

FIG. 3

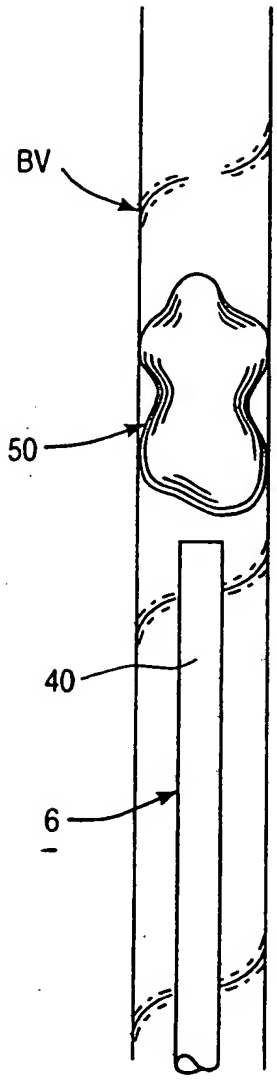

FIG. 4A

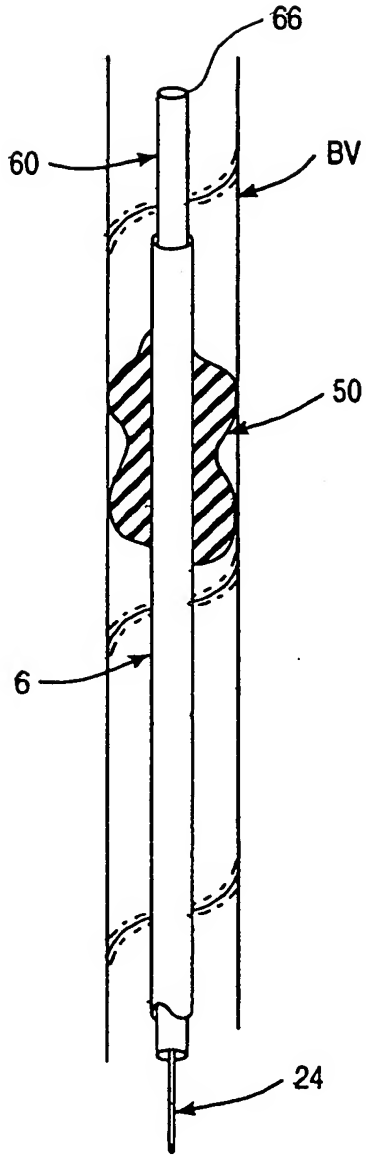

FIG. 4B

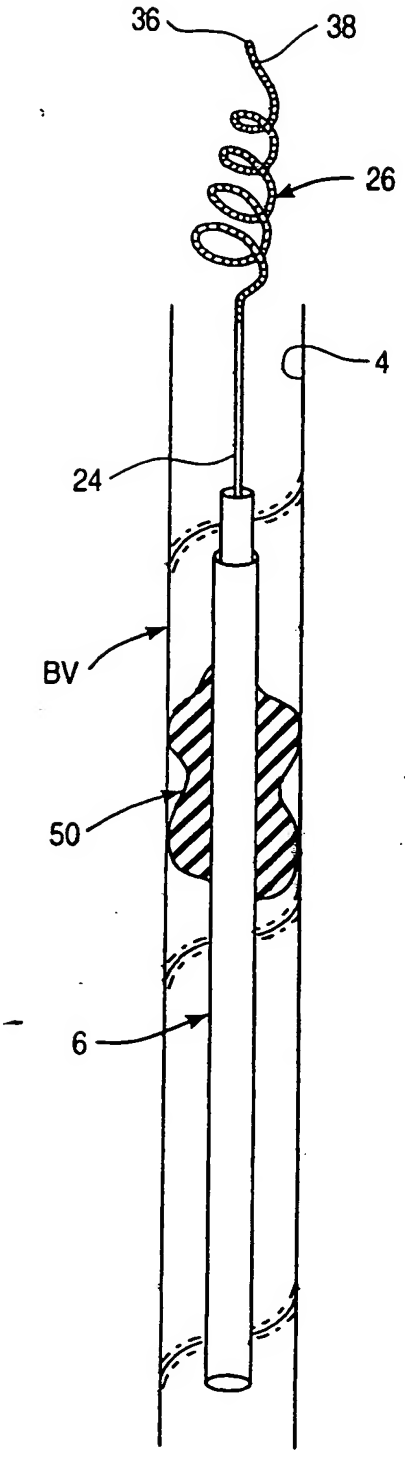

FIG. 4C

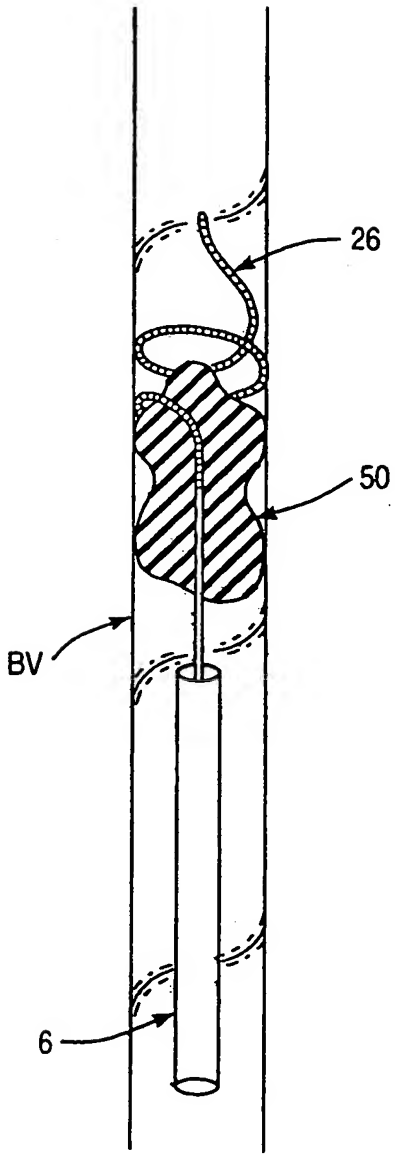

FIG. 4D

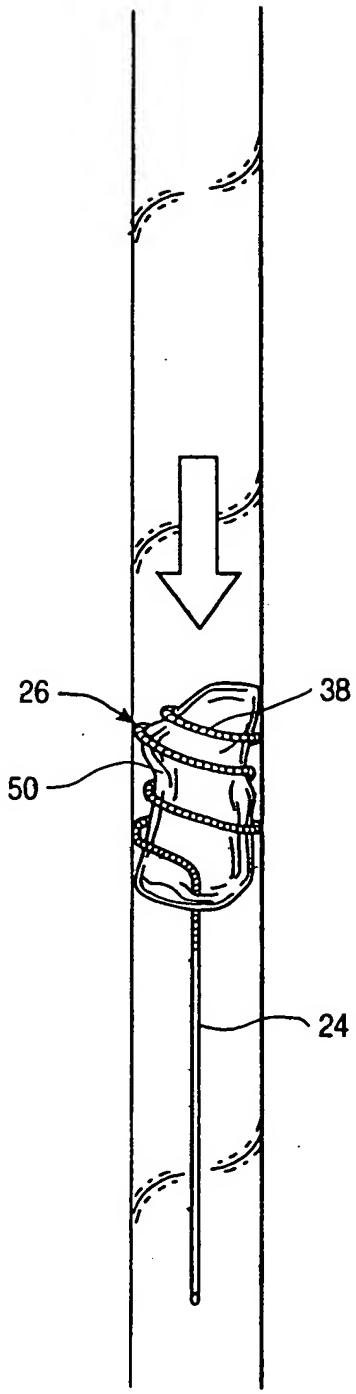

FIG. 4E

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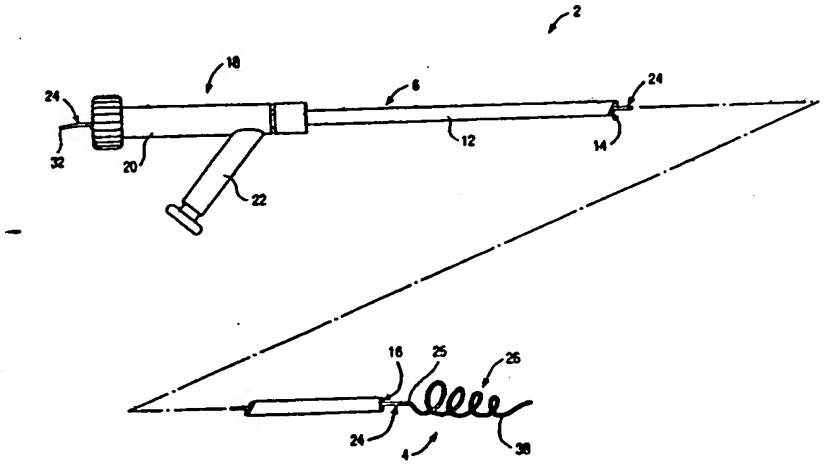

(57) Abstract

Systems, methods and apparatus (2) for removing arteriosclerotic plaque or clots, such as emboli and/or thrombi, from the interior of a fluid vessel, such as a cerebral or coronary artery, are provided. A coil capture device (4) includes a super-elastic coil (26) capable of percutaneously removing plaque and clots from blood vessels without the need for surgical intervention. A radiopaque element (38) is secured over the coil to improve visualization of the coil capture device (4), which enhances the accuracy of the procedure. A hollow introducing sheath (12) is also provided to facilitate the endo-luminal delivery of the coil capture device (4) to the clot region within the patient's vasculature.

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y		1, 2, 7-10, 12-15

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